November 26, 2025

Shanghai United Imaging Healthcare Co., Ltd.
℅ Xin Gao
Regulatory Affairs Manager
No.2258 Chengbei Rd. Jiading District
SHANGHAI, 201807
CHINA

Re: K252000
Trade/Device Name: uDR Arria & uDR Aris
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: October 24, 2025
Received: October 24, 2025

Dear Xin Gao:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252000

Device Name
uDR Arria & uDR Aris

Indications for Use *(Describe)*
Digital Medical X-ray Imaging System is intended to acquire X-ray images of the human body by a qualified technician, examples include acquiring two dimensional X-ray images of the skull, spinal column, chest, abdomen, extremities, limbs and trunk. The visualization of such anatomical structures provide visual evidence to radiologists and clinicians in making diagnostic decisions. This device is not intended for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

UNITED IMAGING

510 (k) SUMMARY

1. **Date of Preparation:**
June 30, 2025

2. **Sponsor Identification**

Shanghai United Imaging Healthcare Co., Ltd.
No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Establishment Registration Number: 3011015597

3. **Contact Person**
Name: Xin Gao
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

4. **Subject Device Name and Classification**

Trade Name: uDR Arria & uDR Aris
Common Name: Digital Medical X-ray Imaging System
Model(s): uDR Arria, uDR Aris

Regulatory Information
Classification Name: Stationary X-Ray System
Device Classification: II
Product Code: KPR
Regulation Number: 21 CFR 892. 1680
Review Panel: Radiology

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

5. Identification of Predicate/Reference Device(s)

Predicate Device:

Trade Name： uDR 596i
510(k) Number: K192293
Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Regulation Number: 21 CFR 892. 1680
Classification: II
Product Code: KPR

Reference Device：

Trade Name: MULTIX Impact E
510(k) Number: K233532
Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: KPR

6. Device Description:

uDR Arria and uDR Aris are two models of Digital Medical X-ray Imaging System developed and manufactured by Shanghai United Imaging Healthcare Co., Ltd(UIH). The system is equipped with imaging chain components and utilizes enhanced processing technology, so it can offer radiographic images with high image quality. The intuitive user interface and easy-to-use functions provide clinical users with a experience during patient examination and image processing.

The system is intended to acquire X-ray images of the human body by a qualified technician, examples include acquiring two-dimensional X-ray images of the skull, spinal column, chest, abdomen, extremities, limbs and trunk. The visualization of such anatomical structures provide visual evidence to radiologists and clinicians in making diagnostic decisions. This device is not intended for mammography.

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

This proposed device includes two models: uDR Arria, uDR Aris. The main differences between the two models are as follows:

Main Component	uDR Arria	uDR Aris
High Voltage Generator		
Generator with key performance: -Max. 40kW output power	/	√
Generator with key performance: -Max. 65kW output power	√	/
Generator with key performance: -Max. 80kW output power	√	/
X-ray Tube Assembly		
Tube with key performance: - Anode Heat Content 230kHU	/	√
Tube with key performance: - Anode Heat Content 300kHU	√	/
Tube with key performance: - Anode Heat Content 400kHU	√	/
Collimator		
Manual	√	√
Motorized	√	/
Flat Panel		
uFPD 1717-100	√	√
uFPD 1417-100	√	√
Patient Table		
Elevating Table	√	√
Optional Software function		
uAid	√	/
uVision	√	/

The main difference between the two models is that only the uDR Aris supports the 40kW output power High Voltage Generator configuration. Other components are all available for uDR Arria.

7. **Intended Use Statement:**

The following statement applies to uDR Arria and uDR Aris：

Digital Medical X-ray Imaging System is intended to acquire X-ray images of the human body by a qualified technician, examples include acquiring two-dimensional

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

X-ray images of the skull, spinal column, chest, abdomen, extremities, limbs and trunk. The visualization of such anatomical structures provide visual evidence to radiologists and clinicians in making diagnostic decisions. This device is not intended for mammography.

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

8. Substantially Equivalent (SE) Comparison

A comparison between the technological characteristics of proposed and predicate devices is provided as below.

Table 1 Comparison of uDR Arria's Technology Characteristics to predicate device

Item	Proposed Device uDR Arria	Predicate Device uDR 596i (K192293)	Remark
General			
Product Code	KPR	KPR	Same
Regulation No.	892.1680	896.1680	Same
Class	II	II	Same
Intended Use	Digital Medical X-ray Imaging System is intended to acquire X-ray images of the human body by a qualified technician, examples include acquiring two-dimensional X-ray images of the skull, spinal column, chest, abdomen, extremities, limbs and trunk. The visualization of such anatomical structures provide visual evidence to radiologists and clinicians in making diagnostic decisions. This device is not intended for mammography.	The uDR 596i Radiographic system is intended to use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, limbs and trunk. Not for mammography.	Note 1
Specifications			
High Voltage Generator			

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Item	Proposed Device uDR Arria	Predicate Device uDR 596i (K192293)	Remark
Max. Power/kW	65kW/80kW	65kW/80kW	Same
Max. tube Voltage(kV)	150kV	150kV	Same
Shortest exposure time	1ms	1ms	Same
X-Ray Tube Assembly			
Focus Nominal Value	0.6/1.2	0.6/1.2	Same
Maximum peak voltage	150kV	150kV	Same
Anode Heat Content	65kw: ≥300kHU 80kw: ≥400kHU	65kw: ≥300kHU 80kw: ≥400kHU	Same
Anode Target Angle	12°	12°	Same
X-ray tube Heat content	65kw: ≥1250KHU 80kw: ≥1339KHU	65kw: ≥1250KHU 80kw: ≥1500KHU	Note 2
Flat Panel Detector-Config.1			
Model	uFPD1717-100	Mars1717XU-VSI	

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Item	Proposed Device uDR Arria	Predicate Device uDR 596i (K192293)	Remark
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	Same
Image Matrix Size	4267x4267 100 μm	3072×3072 139 μm	Note 3
Effective radiographic size	42.7cm x 42.7cm	42.7cm x 42.7cm	Same
Flat Panel Detector-Config.2			
Model	uFPD1417-100	Mars1717XU-VSI	
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI)	Same
Image Matrix Size	3500x4300 100 μm	3072×3072 139 μm	Note 4
Effective Radiographic Size	35cm x 43cm	42.7cm x 42.7cm	Note 5
Collimator Config.1(Manual)			
Inherent filtration	1.0 mmAl@75 kV	1.0 mmAl@75kV	Same

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Item	Proposed Device uDR Arria	Predicate Device uDR 596i (K192293)	Remark
Copper prefilter	without filter, 0.1mm, 0.2mm, 0.3mm;	without filter, 0.1mm, 0.2mm	Note 6
Motorized Field of View Control	No	No	Same
Automatic SID Adjusted Collimation	No	No	Same
Collimator Config.2 (Motorized)			
Inherent filtration	1mm Al @75 kV	1mm Al @75 kV	Same
Copper prefilter	without filter, 0.1 mm, 0.2 mm, 0.3 mm;	without filter, 0.1 mm, 0.2 mm	Note 7

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Item	Proposed Device uDR Arria	Predicate Device uDR 596i (K192293)	Remark
Motorized Field of View Control	Yes	No	Note 8
Automatic SID Adjusted Collimation	Yes	No	Note 9
Bulit-in camera	Live 2D Camera for patient positioning and collimation	N.A.	Note 10
Software function			
Stitching	Yes	Yes	Same
Automatic exposure control (AEC)	Yes	Yes	Same
Safety			
Electrical Safety	ANSI/AAMI ES 60601-1:2005 & A1:2012 & A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	ANSI/AAMI ES 60601-1:2005 & A1:2012 & A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Same
EMC	Comply with IEC 60601-1-2:2014+A1:2020	Comply with IEC60601-1-2	Same

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Item	Proposed Device uDR Arria	Predicate Device uDR 596i (K192293)	Remark
Biocompatibility	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Same
Clinical Image Evaluation	Clinical Image Evaluation for the proposed device are provided in Section 11.5 Clinical Image Evaluation.		
Standards			
DICOM	DICOM3	DICOM3	Same
Power Source	AC Line, Various voltages available	AC Line, Various voltages available	Same

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Table 2 Comparison of uDR Aris's Technology Characteristics to predicate device

Item	Proposed Device uDR Aris	Reference Device Multix Impact E (VB10) (K233532)	Remark
General			
Product Code	KPR	KPR	Same
Regulation No.	892.1680	896.1680	Same
Class	II	II	Same
Intended Use	Digital Medical X-ray Imaging System is intended to acquire X-ray images of the human body by a qualified technician, examples include acquiring two-dimensional X-ray images of the skull, spinal column, chest, abdomen, extremities, limbs and trunk. The visualization of such anatomical structures provide visual evidence to radiologists and clinicians in making diagnostic decisions. This device is not intended for mammography.	MULTIX Impact E is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact E enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and obese patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact E uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact E is also designed to be used with conventional film/screen or	Note 11

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Item	Proposed Device uDR Aris	Reference Device Multix Impact E (VB10) (K233532)	Remark
		Computed Radiography (CR) cassettes. MULTIX Impact E is not intended for mammography.	
Specifications			
High Voltage Generator			
Max. Power/kW	40kW	40kW	Same
Max. tube Voltage(kV)	150kV	150kV	Same
Shortest exposure time	1ms	1ms	Same
X-Ray Tube			
Focus Nominal Value	0.6/1.2	0.6/1.2	Same
Maximum peak voltage	150kV	150kV	Same
Anode Heat Content	230KHU	230KHU	Same
Anode Target Angle	12°	12°	Same

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Item	Proposed Device uDR Aris	Reference Device Multix Impact E (VB10) (K233532)	Remark
X-ray tube Heat content	1250KHU	1350KHU	Note 12
Automatic exposure control (AEC)	Yes	Yes	Same
Patient Table			
Elevating Table	Yes	Yes	Same
Patient Weight	320kg	300kg	Note 13

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Table 3 Comparison of uDR Arria's new features to reference device

Item	Proposed Device uDR Arria	Reference Device Multix Impact E (VB10) (K233532)	Remark
uVision Function （optional）	Users can manually adjust FOV and stitching range on the workstation. To assist the users with setting the FOV and stitching range, exam range is automatically planned for chest and stitching range is automatically planned for WholeSpine & WholeLowerExtremity.	- Virtual Collimation Manually adjust collimation size on imaging system by 3D camera - Smart Virtual Ortho: Ortho range set by 2D camera in the image system manually - Auto Thorax Collimation Exam range automatically planned for Thorax by 3D camera with manual adjustment - Auto Full-Spine& Long-Leg Collimation: Ortho range automatically planned for Full-Spine &Long-Leg by 2D camera with manual adjustment	Note 14
uAid	Yes	No	Note 15

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Patient Table			
Elevating Table	Yes	Yes	Same
Patient Weight	320kg	300kg	Note 16

Justification	
Note 1	Rephrase the sentence only, the meaning remains the same.
Note 2	X-ray tube heat content represents the maximum amount of heat fusion in the limiting state of the tube. The system is configured with corresponding heat dissipation design and power optimisation, so that the tube will not reach its limiting state during clinical use. The difference does not introduce safety and effectiveness issues.
Note 3	The larger image matrix size, and smaller pixel size. The difference does not introduce safety and effectiveness issues.
Note 4	The larger image matrix size, and smaller pixel size. The difference does not introduce safety and effectiveness issues.
Note 5	Effective Radiographic Size refers to the actual area size of the detector panel that can be utilized in practical imaging. A larger Effective Radiographic Size indicates that the detector can cover a larger range of anatomical areas in practical use. The difference does not introduce safety and effectiveness issues.
Note 6	Copper filtration removes lower energy X-ray photons, which do not enhance image quality but would otherwise contribute to patient radiation dose. Compared to the predicate device, the proposed device provides

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

	an additional 0.3mm copper prefilter option, which not only reduces the radiation dose, but also meets more clinical requirements. The difference does not introduce safety and effectiveness issues.
Note 7	Copper filtration removes lower energy X-ray photons, which do not enhance image quality but would otherwise contribute to patient radiation dose. Compared to the predicate device, the proposed device provides an additional 0.3mm copper prefilter option, which not only reduces the radiation dose, but also meets more clinical requirements. The difference does not introduce safety and effectiveness issues.
Note 8	The motorized collimator supports automatically FOV setting via the preset value in organ program, offering users better usability compared to the predicate device. The difference does not introduce safety and effectiveness issues.
Note 9	Under different SID, with the motorized collimator, the lead leaves of the collimator on the proposed device can automatically adjust the aperture size to maintain the FOV the same. The difference does not introduce safety and effectiveness issues.
Note 10	2D camera only introduced to capture optical information and support more clinical operational possibilities., does not affect safety and effectiveness.
Note 11	Rephrase the sentence only, the meaning remains the same.
Note 12	X-ray tube heat content represents the maximum amount of heat fusion in the limiting state of the tube. The system is configured with corresponding heat dissipation design and power optimisation, so that the tube will not reach its limiting state during clinical use. The difference does not introduce safety and effectiveness issues.
Note 13	Compared to the predicate device, the patient weight has been increased, enabling the system more flexibility and a broader range of patient. The difference does not introduce safety and effectiveness issues.

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Note 14	For manually adjust collimation size and automatically planned for chest and stitching range these two functions are same with predicate device MULTIX Impact E, the difference is the description, the difference does not introduce safety and effectiveness issues.
Note 15	uAid evaluates the positioning quality of chest images with deep learning methods. It efficiently and objectively categorizes images into three levels according to four criteria, assist technologist for image acquisition. The difference does not introduce safety and effectiveness issues.
Note 16	Compared to the predicate device, the patient weight has been increased, enabling the system more flexibility and a broader range of patient. The difference does not introduce safety and effectiveness issues.

9. Non-Clinical Test Conclusion

9.1 Performance Evaluation

Non clinical tests were conducted to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI/AAMI ES 60601-1:2005 & A1:2012 & A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3:2008+A1:2013+A2:2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-2-54:2022 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.
- IEC 60601-2-28:2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

Additional non-clinical tests are conducted for key features to ensure safe and effectiveness when integrated into the system:

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

Feature	Bench Testing Performed
uVision	**Introduction** The uVision algorithm in the digital medical X-ray imaging system (uDR Arria) aims to optimize the radiographic scanning workflow through patient positioning recognition technology. This algorithm utilizes cameras to capture natural images of the human body, achieving multi-modal real-time automatic localization of key anatomical points, body modeling, and pose estimation for patients. It provides the system with scanning positions, ranges, and generates motion trajectory plans for DR racks. **Acceptance Criteria** As an auxiliary function designed to enhance clinical workflow efficiency, uVision is expected to assist users in completing pre-exposure positioning tasks. In the context of chest X-ray imaging, the retake rate due to incorrect positioning is a critical quality control metric. According to relevant studies and literature, incorrect positioning is one of the primary causes of retakes. By a 5-month-long observation experiment, positioning error results in approximately 9% rejection in DR. Furthermore, some literature indicates that positioning errors contribute to 28% of rejections. The specific figures may vary depending on the healthcare institution, equipment type, and technician experience. Considering the impact of camera specifications and gantry control accuracy on the application of uAI vision algorithm to DR equipment, we expect that when users employ the uVision function for automatic positioning, the automatically set system position and field size will meet clinical technicians' criteria with 95% compliance, thereby demonstrating that uVision can effectively assist clinical technicians in positioning tasks. **Testing Data Information** The device with uVision function has been tested, with equipment serial number 11XT7E0001. Since the installation and commissioning over a year ago, the average daily imaging volume on the device has been around 80 patients, with approximately 45 chest X-rays per day and about 10 to 20 stitching cases per week. After receiving specialized training prior to use, the technicians operating this equipment utilize the uVision function to set the FOV and system position when conducting chest PA, whole-spine, and whole-lower-limb stitching exams.

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

The results automatically set by the system are then statistically analyzed by clinical experts .

Testing data includes individuals of all genders and varying heights (capable of standing independently)

Height (m)	≤1.25	1.25~1.5	1.5~1.75	≥1.75
Percentage	3%	7%	58%	32%

Table presents the evaluation results of the imaging positioning sampled randomly over a period since the equipment was put into use.

Table . The evaluation results of uVision automatically system positioning and FOV setting for chest PA、WholeSpine and WholeLowerExtremity

Date	Chest/case	Case of Non-Compliant Cases in System-Automatically Set Results	Full Spine or Full Lower Limb Stitching/case	Case of Non-Compliant Cases in System-Automatically Set Results
2024.12.17	62	3	2	0
2024.12.18	44	3	2	0
2024.12.19.	35	2	5	0
2024.12.20	18	1	5	0
2024.12.21	59	2	2	0
2024.12.22	47	1	1	0
2024.12.23	63	2	3	0

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

<table>
<tr><td></td><td>
<table>
<tr><td>Total number of cases in a week</td><td>328</td><td>14</td><td>20</td><td>0</td></tr>
</table>
Equipment and Protocols
The test data was collected from hospital, and the testing protocol included chest, Whole-spine stitching, Whole-Lower-extremity stitching.
Clinical Subgroups
No clinical subgroups and confounders have been defined for the datasets.
Testing & Training Data Independence
The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data is entirely independent and does not share any overlap with the training data.
Summary
According to the results of the current equipment statistics, in 95% of patient positioning processes, the light field and equipment position automatically set by uVision can meet the clinical positioning and shooting requirements. In the remaining 5% of cases, based on the light field and system position automatically set by the equipment, technicians still need to make manual adjustments</td></tr>
<tr><td>uAid</td><td>Introduction
uAid is used for checking the quality of examination and positioning. The results can help to assist with departmental management functions. uAid is triggered after the acquisition of chest X-ray images in patients aged over 20 years, which automatically evaluates image characteristics against four criteria, namely whether there is a foreign object, whether the lung field is complete, whether the scapula is open, and whether the spine is located on the center line, categorizing images into one of three quality levels. The outcome of the evaluation is instantly accessible to radiologic technologists, reminding them to verify that the image meets the image quality control. It bears emphasis that the result of image quality control is for reference only and cannot be used as the basis for clinical diagnosis.
Acceptance Criteria
uAid is designed to provide an objective image evaluation method, offering hospitals a unified assessment tool to manage images/technicians. The accuracy of non-standard image</td></tr>
</table>

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

recognition is a key quality control metric. According to relevant research and literature, the rate of Grade A clinical images is typically influenced by factors such as the technician's operational standardization, equipment performance, and quality control processes, with variations observed across different levels of medical institutions and equipment types. Mature industry guidelines and standards, such as those from European Radiology and the ACR-AAPM-SPR Practice Parameter, indicate that the Grade A image rate in public hospitals generally ranges between 80% and 90%. To ensure uAid's functionality meets clinical requirements, we referenced these guidelines and set a 90% pass rate, aligning with industry standards. This demonstrates that uAid can effectively assist clinical technicians in managing standardized image quality.

Testing Data Information

The data collection started in October 2017, with a wide range of data sources. Some of the data come from different cooperative hospitals. After multiple cleaning and sorting, the data is stored in DICOM format. The study was approved by the institutional review board of the hospitals.

It does not include data on DR-sensitive groups such as infants and young children, and is only applicable to frontal chest images.

- Age and gender distribution of data sets for uAid：

Age	**Male**	Female
20-29	310	698
30-39	308	744
40-49	298	798
50-59	385	801
60-69	320	799
70-79	200	472
80-89	97	210
90-99	21	46
No Age	97	187
No Age，No Gender	45	

- Distribution of negative and positive data for uAid:

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

	Negative	Positive
lung field segmentation	465	31
Spinal centerline segmentation	815	68
Shoulder blades segmentation	210	1089
Foreign object	1078	3080

Equipment and Protocols:

The data collection started in October 2017 on the uDR 780i, with a wide range of data sources. Some of the data come from different cooperative hospitals.

Clinical Subgroups:

No clinical subgroups and confounders have been defined for the datasets.

Testing & Training Data Independence

The testing dataset was collected independently from the training dataset, with separated subjects and during different time periods. Therefore, the testing data is entirely independent and does not share any overlap with the training data.

Summary：

Test dataset analysis results are summarized as below:

1. The average time of the uAid algorithm is 1.359 seconds, and the longest does not exceed 2 seconds;
2. The maximum memory occupation of uAid algorithm is not more than 2G;
3. For uAid, the sensitivity and specificity of whether there is a foreign body, whether the lung field is intact, and whether the scapula is open all exceed 0.9;

The uAid function can correctly identify four types of results: Foreign object, Incomplete lung fields, Unexposed shoulder blades, and Centerline deviation and make classification after the exposure image is generated: Green (qualified image), yellow (secondary image), red (waste image).

uAid can meet the requirement which is used for checking the quality of examination and position for institutions. The results can assist the image quality assessment with departmental management functions.

Shanghai United Imaging Healthcare Co., Ltd.

Tel: +86 (21) 67076888 Fax: +86 (21) 67076889

www.united-imaging.com

9.2 Clinical Image Evaluation

The clinical image evaluation was performed under the proposed device. Sample images of chest, abdomen, spine, pelvis, upper extremity and lower extremity were provided with a board certified radiologist to evaluate the image quality in this submission. Each image was reviewed with a statement indicating that image quality is sufficient for clinical diagnosis.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the technology characteristics of the modified uDR Arria, uDR Aris reflected in this 510(k) submission, do not alter the scientific technology of the devices and are substantially equivalent to those of the predicate devices.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, we conclude that the uDR Arria, uDR Aris Stationary X-Ray Systems are substantially equivalent to the predicate devices. It does not introduce new indications for use, and has the same technological characteristics and does not introduce new potential hazards or safety risks.